

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW HAMPSHIRE**

LISA D. CARPENTER  
and JEFFREY D. CARPENTER

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana  
corporation,

Defendant.

Case No. 1:14-cv-00540-AJ

**DEFENDANT LILLY'S MOTION FOR JUDGMENT ON THE PLEADINGS UNDER  
FED. R. CIV. P. 12(C)**

Defendant Eli Lilly and Company (“Lilly”) hereby moves for judgment on the pleadings under Federal Rule of Procedure 12(c) based on the doctrine of preemption. As explained in Lilly’s supporting memorandum of law, Plaintiffs Lisa D. Carpenter and Jeffrey D. Carpenter bring state-law claims against Lilly in two categories: (i) they allege that the prescribing information for Cymbalta approved by the federal Food and Drug Administration (“FDA”) inadequately warns against the risk of adverse symptoms that can accompany discontinuing Cymbalta, and (ii) they allege that Lilly’s FDA-approved design for Cymbalta is defective. *See* Compl. (Dkt. No. 1) (Dec. 3, 2014) ¶ 1.

As governing First Circuit and Supreme Court precedent make clear, both claims here are preempted by the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 et seq. For both the warning claim and design-defect claim, Plaintiffs’ Complaint taken as true would impermissibly obligate Lilly to alter its FDA-approved warnings and design when the governing regulatory structure would prohibit such unilateral action in this situation. The First Circuit’s recent decision in *In re Celexa* confirms that Plaintiffs’ state-law claims must yield to competing federal-law duties and thus fail as a matter of law. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 40-43 (1st Cir. 2015); *see also Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2477–78 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580–81 (2011). In harmony with this Circuit and the Supreme Court’s binding authority, and in a straightforward application of what is now hornbook preemption doctrine, this Court should grant Lilly’s motion for judgment on the pleadings. *See* Fed. R. Civ. P. 12(c).

**First**, Plaintiffs’ state-law failure-to-warn claims are preempted because they seek to require Lilly to unilaterally change its FDA-approved label for Cymbalta to include information that was already fully in the possession of the FDA when it approved Cymbalta and its labeling. Plaintiffs allege that the label inadequately conveys the risks of discontinuing Cymbalta, and that

the label's inadequate discontinuation warning injured Plaintiffs. *See* Compl. ¶¶ 1, 37-43, 53-103. "[A]s the complaint reads, [Lilly] would need to change [Cymbalta's] label in order to avoid liability under state law." *See In re Celexa*, 779 F.3d at 40. At the same time, however, the FDCA prohibits manufacturers from unilaterally changing labels that the FDA has approved, unless the change fits within the category of changes that a manufacturer can make independently through the FDA's Changes Being Effectuated ("CBE") provision. *See id.* at 38. This narrow exception permits a manufacturer to change a label without FDA approval *only if* the change reflects "newly acquired information." *See id.* Yet, according to their own allegations on the face of the Complaint, Plaintiffs seek to have Lilly change its discontinuation warning to reflect information and data (on the frequency, severity, and duration of discontinuation symptoms) that Lilly presented to the FDA and that the FDA fully considered *before* the medicine and its labeling were ever approved. *See, e.g.,* Compl. ¶¶ 16, 18, 21, 22, 71, 82. By Plaintiffs' own allegations, then, Plaintiffs seek to have Lilly change its discontinuation warning based on information that by definition is not "newly acquired." The CBE mechanism, in turn, is unavailable to Lilly, meaning that "[Lilly] could not independently change its label to read as [Plaintiffs] say it should have read in order to comply with [state] law." *See In re Celexa*, 779 F.3d at 43. Plaintiffs' failure-to-warn claims must therefore yield to federal law.

**Second**, Plaintiffs' state-law design-defect claims are preempted because they seek to unilaterally require Lilly to alter its design for Cymbalta. Plaintiffs allege that, instead of designing, manufacturing, and distributing Cymbalta in its only FDA-approved forms (20-, 30-, or 60-milligram capsules), Lilly should have designed and produced the medicine in capsules containing smaller doses or in a different dosage form entirely, such as a scored tablet or a liquid. Compl. ¶¶ 1, 19, 24, 48-49. Federal law, however, affords Lilly *no* way to implement Plaintiffs' proposed alternative design without the FDA's approval. Once the FDA approves the new-drug

application for a particular medicine, the manufacturer is absolutely prohibited from unilaterally making any “changes in the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.” 21 C.F.R. § 314.70(b)(2)(i). Plaintiffs’ design-defect claims, if taken as true, would make it impossible for Lilly to comply with both state and federal requirements. Federal law thus preempts these claims, as well.

For the foregoing reasons, and based on (i) this Motion, (ii) Lilly’s supporting memorandum of law, and (iii) the supporting Declaration of Michael X. Imbroscio, including exhibits, the Court should grant Lilly’s Rule 12(c) motion for judgment on the pleadings and dismiss Plaintiffs’ Complaint with prejudice.

DATED: May 22, 2015

Respectfully Submitted,

/s/ Michele E. Kenney

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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Motion for Judgment on the Pleadings Under Fed. R. Civ. P. 12(c) was sent this 22nd day of May, 2015, via ECF to Leslie C. Nixon, Esquire, and Robert B. Wisner, counsel of record.

/s/ Michele E. Kenney  
Michele E. Kenney